

Failure Mode & Effect Analysis (FMEA)

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Objectives

- FMEA Terms
- What is FMEA ?
- Why FMEA ?
- Types of FMEA
- History
- FMEA Form
- Who uses FMEA
- Procedure
- RPN
- Implementation into design Process
- Severity
- Occurrence
- Detection
- Example, Limitation, Advantages

Fmea terms

☐ Failure

- The loss of a function under stated conditions.

☐ A Failure Mode is:

- The way in which the components, subassembly, product, input, or process could fail to perform its intended function.
- Things that could go wrong.
- Example: A fully fractured axle.

☐ Effects analysis

- Studying the consequences of the various failure modes to determine their severity to the customer.

What is Fmea ?

- ❑ **Failure Mode and Effect Analysis (FMEA)** is a step by step approach for identifying all possible failures in a design, a manufacturing or a product or service.
- ❑ FMEA is an inductive reasoning (forward logic).
- ❑ It is a core task in Reliability Engineering, Safety Engineering and Quality Engineering.
- ❑ It is based on experience with similar product or process or based on common Physics of failure logic.
- ❑ Sometimes FMEA is Extended to FMECA to indicates that criticality analysis is performed too.

Why fmea ???

- ☐ Methodology that facilitates Process Improvement.
- ☐ Improve internal and external customer satisfaction.
- ☐ Focuses on prevention.
- ☐ Identifying and eliminates concerns early in the development of process or design.
- ☐ FMEA may be a customer requirement (likely contractual)
- ☐ FMEA may be required be an applicable
Quality Management System Standard (possibly ISO)

Types of FMEa

- ❑ Design – focuses on component and subsystems.
- ❑ Process – focuses on Manufacturing and Assembly processes.
- ❑ System – focuses on global system functions.
- ❑ Service – focuses on service functions.
- ❑ Software – focuses on software functions.

History of fmea

- ❑ An offshoot of 1949 Military Procedure MIL-P-1629, entitled “Procedures for Performing a Failure Mode, Effects and Criticality Analysis”
- ❑ Used as a reliability evaluation technique to determine the effect of system and equipment failures.
- ❑ Failures were classified according to their impact on mission success and personnel/equipment safety.
- ❑ Formally developed and applied by NASA in the 1960’s to improve and verify reliability of space program hardware.
- ❑ The procedures called out in MIL-STD-1629A are the most widely accepted methods throughout the military and commercial industry.

The fmea form

Process/Product Failure Modes and Effects Analysis Form (FMEA)

Prepared by:	Page ____ of ____
FMEA Date (Orig) _____ (Rev) _____	

Process Step / Input	Potential Failure Mode	Potential Failure Effects	SEVERITY	Potential Causes	OCCURRENCE	Current Controls	DETECTION	RPN	Actions Recommended	Resp.	Actions Taken	SEVERITY	OCCURRENCE	DETECTION	RPN
What is the process step and input under investigation?	In what ways does the Key Input go wrong?	What is the impact on the Key Output Variables (Customer Requirements)?		What causes the Key Input to go wrong?		What are the existing controls and procedures (inspection and test) that prevent either the cause or the Failure Mode?			What are the actions for reducing the occurrence of the cause, or improving detection?		What are the completed actions taken with the recalculated RPN?				
								0							0
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Identify failure modes and their effects

Identify causes of the failure modes and controls

Prioritize

Determine and assess actions

Who uses FMEA ???

☐ Engineers Worldwide in :

- Nuclear Power plant.
- Aerospace
- Chemical Process Industries
- Automotive Industries

☐ Healthcare

☐ Goal has been, and remains, to prevent accident accidents from occurring

Fmea: a team tool

- ☐ A Team approach is necessary.
- ☐ Team leader should be familiar with FMEA.
- ☐ The following should be considered for team members:
 - I. Design Engineers
 - II. Process Engineers
 - III. Materials Suppliers
 - IV. Operators
 - V. Reliability
 - VI. Suppliers
 - VII. Customers

Fmea Procedure

1. Determine failure mode for each process input.
2. For each failure mode, determine effects – Select a severity level for each effect.
3. Identify potential causes of each failure mode – Select an occurrence level for each cause.
4. List current controls for each cause – Select a detection for each cause.
5. Calculate the Risk Priority Number (RPN).
6. Develop recommended action , assign responsible person and take actions.
7. Assign the predicted Severity, Occurrence and Detection levels and compare RPNs

Risk Priority number (rpn)

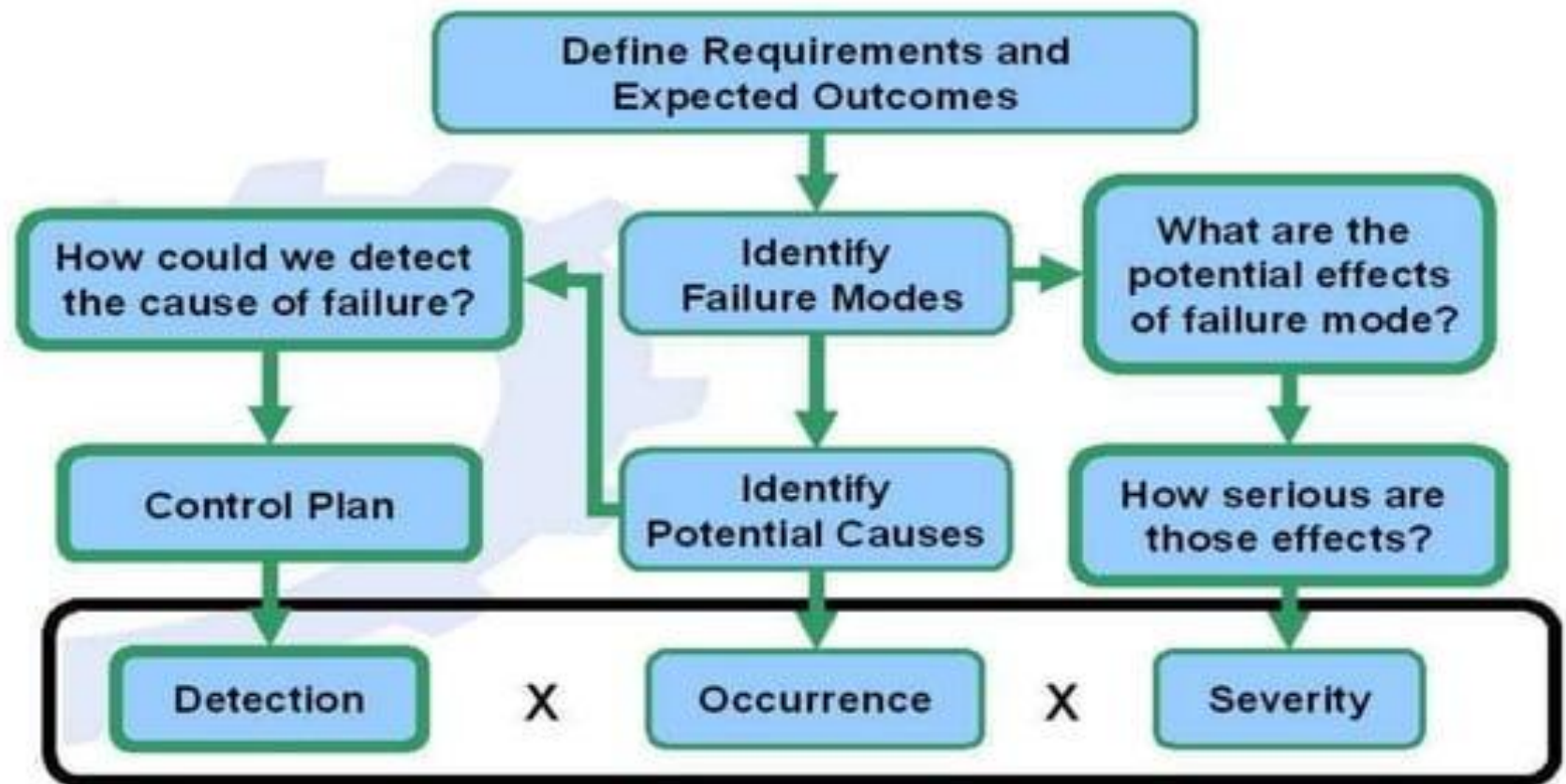
$$\square \text{Severity} \times \text{Occurrence} \times \text{Detection} = \text{RPN}$$

- 1000 is maximum and 75* is considered OK!!!
- Severity (S)
 - Importance of the effects on customer requirements.
 - 1 = Not sever, 10 = very sever
- Occurrence (O)
 - Frequency with which a given cause occurs and creates failure modes.
 - 1 = NOT Likely, 10 = Very Likely
- Detection (D)
 - The ability of the current control scheme to detect then prevent a given causes.
 - 1 = Easy to Detect, 10 = Not easy to Detect

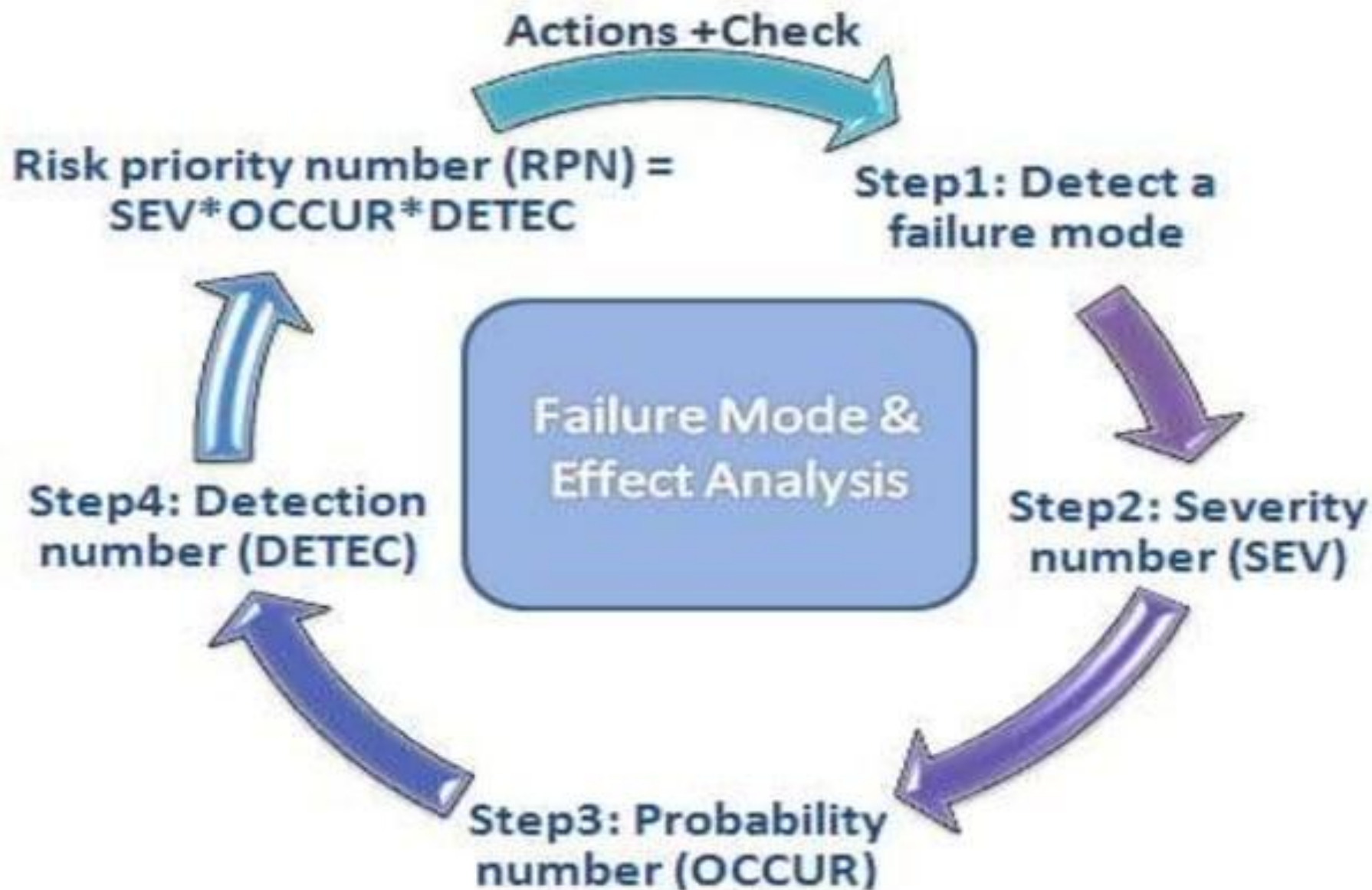
Risk Priority number (rpn)

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Risk Priority Number



Risk Priority number (rpn)



Rating Scales

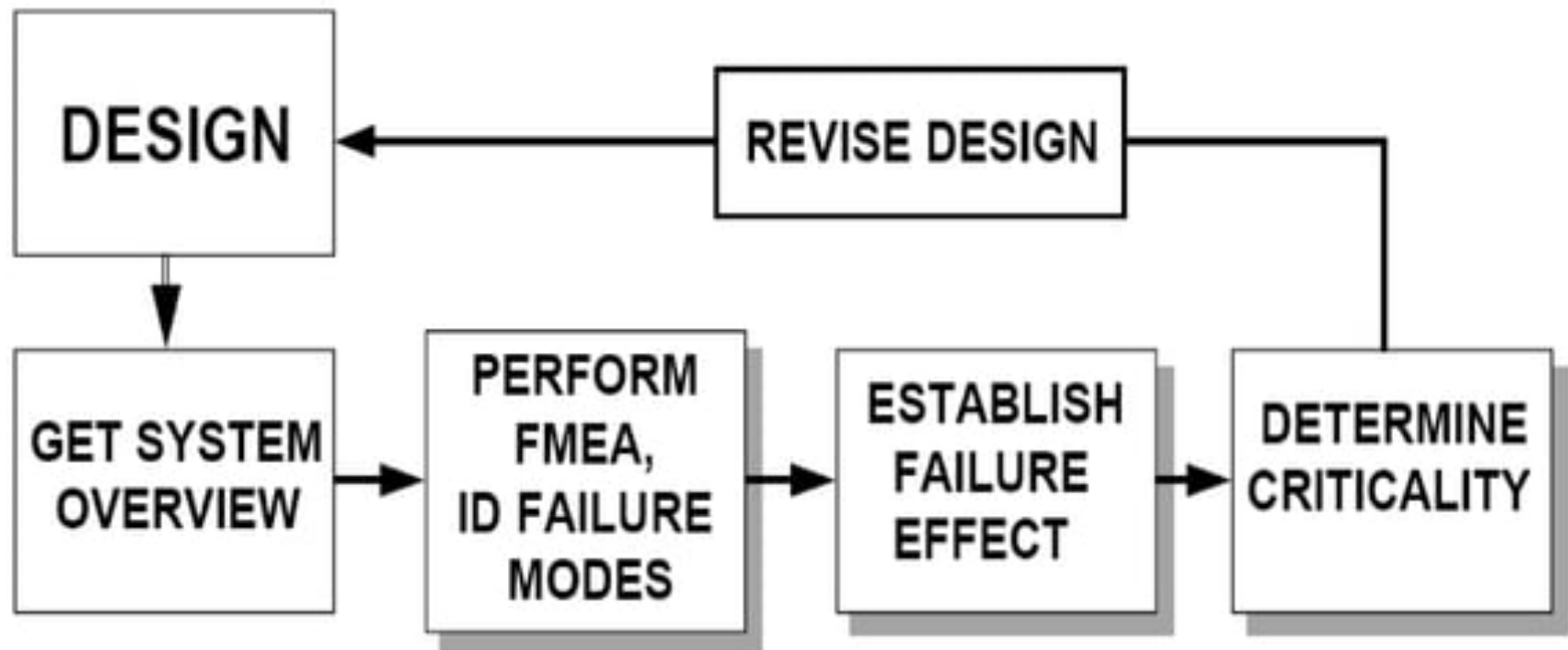
- ☐ There are a wide variety of scoring anchors.
- ☐ Two types of scales are 1-5 or 1-10.
- ☐ The 1-5 scale makes it easier for the teams to decide on scores.
- ☐ The 1-10 scale may allow for better precision in estimates and a wide variation in scores.
- ☐ Zero(0) Ranking not allowed for RPN Rating Scales.

Fmea timing

❑ FMEA should be updated –

- At the conceptual stage.
- When changes are made to the design.
- When new regulation are instituted.
- When customer feedback indicates a problem.

Implementation into Design process



Severity Evaluation Criteria

Effect	Criteria: Severity of Effect	Rank
Hazardous - without warning	Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning	10
Hazardous - with warning	Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning	9
Very High	Vehicle/item inoperable, with loss of primary function.	8
High	Vehicle/item operable, but at reduced level of performance. Customer dissatisfied.	7
Moderate	Vehicle/item operable, but Comfort/ Convenience item(s) inoperable. Customer experiences discomfort.	6
Low	Vehicle/item operable, but Comfort/ Convenience item(s) operable at reduced level of performance. Customer experiences some dissatisfaction.	5
Very Low	Fit & finish/Squeak & Rattle item does not conform. Defect noticed by average customers.	4
Minor	Fit & finish/Squeak & Rattle item does not conform. Defect noticed by most customers.	3
Very Minor	Fit & finish/Squeak & Rattle item does not conform. Defect noticed by discriminating customers.	2
None	No effect.	1*

Ranking of Occurrence of Effect

Probability of Failure	Possible Failure rates	Ranking
Very High : Persistent failure	≥ 100 per thousand cores	10
	50 per thousand cores	9
High : Frequent failure	20 per thousand cores	8
Moderate : Occasional failure	10 per thousand cores	7
	5 per thousand cores	6
	2 per thousand cores	5
Low : Relatively few failure	1 per thousand cores	4
	0.5 per thousand cores	3
Remote : Failure is unlikely	0.1 per thousand cores	2
	≤ 0.01 per thousand cores	1*

Suggested Detection Evaluation Criteria		
Detection	Criteria	Rank
Absolute Uncertainty	Design Control will not and/or cannot detect a potential cause/mechanism and subsequent failure mode; or there is no Design Control.	10
Very Remote	Very Remote chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	9
Remote	Remote chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	8
Very Low	Very Low chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	7
Low	Low chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	6
Moderate	Moderate chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	5
Moderately High	Moderately High chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	4
High	High chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	3
Very High	Very High chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	2
Almost Certain	Design Controls will almost certainly detect a potential cause/mechanism and subsequent failure mode.	1*

FMEA OF A BALL POINT PEN

Fmea table for ball-point pen

Part	Function	Potential failure Mode	Potential Effect of failure	S E V E R I T Y	Potential Causes of failure	O C C U R R A N C E	How will the potential failure be Detected ?	D E T E C T I O N	RPN	ACTIONS
Outer Tube	Provides grip for writer	Hole gets blocked	Vacuum on ink supply stops flow	7	Debris ingress into hole	3	Check clearance of hole	5	105	Make hole larger
Ink	Provides writing medium	Incorrect Viscosity (Low)	High flow	4	Too much solvent	2	QC on ink supply	4	32	Introduce more rigid QC
Ink	Provides writing medium	Incorrect Viscosity (High)	Low flow	4	Too little solvent	2	QC on ink supply	3	24	Introduce more rigid QC

Fmea for Boiler tube

Year	No. of Failure
2009	A = 24 (Assume)
2010	B = 22
2011	C = 26
2013	D = 23
2014	E = 19
2015	—

Risk Analysis of Boiler using Failure Mode & Effect Analysis

Potential failure mode	Potential effect of failures	Potential causes	Severity (S)	Occurrence (O)	Detection (D)	RPN	Control Process Detection
Boiler Tube	1. Water leakage 2. Cooling process stop 3. Unit had shut down 4. Water level not maintained	1. Corrosion 2. Scale formation 3. Extremely combustion 4. Creep failure 5. Poor water Circulation	X = 9 (let)	Y = 7 (let)	Z = 5 (let)	315	Water leakage
							Thickness of tube wall
							Thermal stress
							Increased tube strain
							Alarms

HFmea Example

- ❑ Suppose A Person who was a patient in the SMS Hospital, Jaipur. He/she died suddenly cause of **Swine Flu** in the presence of her physician and member of him/her family. He/she was alert and oriented at the time and him/her condition, while very serious, did not seem to indicate reason for immediate concern. Him/her unexpected death was devastating for her family and extremely distressing for all those involved in her care.
- ❑ An ICU physician suspected the cause - the composition of solution being used to treat him/her failure. This was quickly confirmed and 30 bags of the solution made in the same batch were removed from patient care areas, undoubtedly preventing the deaths of other patients and investigation that how to solve detected problem.

Advantages

- ☐ Enhance design and manufacturing efficiencies
- ☐ Minimize exposure to product failures
- ☐ Augment business records
- ☐ Improve “bottom line” results
- ☐ Add to customer satisfaction
- ☐ Reliability also Improve

Limitation

- ☐ Employee training requirements
- ☐ Initial impact on product and manufacturing schedules
- ☐ Financial impact required to upgrade design, manufacturing, and process equipment and tools

References

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Thank

You!!!